


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 16114-WO-03 | FOR FURTHER ACTION | | See Form PCT/IPEA416 |
| International application No. PCT/IL2005/000086 | International filing date (day/month/year) 24.01.2005 | Priority date (day/month/year) 26.01.2004 | |
| International Patent Classification (IPC) or national classification and IPC INV. A61C5/02 | | | |
| Applicant HOF, Rephael et al. | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 10 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | |
| Date of submission of the demand 13.11.2005 | | Date of completion of this report 08.06.2006 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized officer Salvatore, C Telephone No. +49 89 2399-7194 | |



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-32 as originally filed

Claims, Numbers

1-30 received on 14.11.2005 with letter of 07.11.2005

Drawings, Sheets

1/14-14/14 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 28-30

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).
- ☒ no international search report has been established for the said claims Nos. 28-30
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|---------|
| Novelty (N) | Yes: Claims | 1-27 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | 1-24,27 |
| | No: Claims | 25,26 |
| Industrial applicability (IA) | Yes: Claims | 1-27 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

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Re Item III

Claims 28-30 contain explicit and implicit references to a method which involves necessary surgical procedures to be carried out on a human being, contrary to Rule 39.1 PCT. As such, these claims have not been searched and subsequently were not examined.

Re Item IV

Independent claim 24, although novel over the prior art cited, is not unitary with claims 1 and 25. The reason for this is that there are no technical features common to both claim 1 (or claim 25) and claim 24, and there is no common inventive concept linking the two. In other words, the apparatus of claim 24 could be carried out in/with an instrument which is NOT the same as that of either claim 1 or claim 25.

Independent claim 25 is also non unitary with claim 1 and claim 24 following the same reasoning as that for claim 24.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1 : US 2003/044752 A1 (FISCHER DAN E ET AL) 6 March 2003 (2003-03-06)

D2 : US-B1-6 343 929 (FISCHER DAN E) 5 February 2002 (2002-02-05)

D3 : US-B1-6 340 027 (HAGNE LEIF ET AL) 22 January 2002 (2002-01-22)

2. **Novelty, Art. 33(2) PCT:**

- 2.1 The present application does not meet the requirements of Art. 33(2) PCT because the subject matter of claims 25,26 are not inventive in the sense of Art. 33(3) PCT.

Prior arts D1 and D2 differ from claim 25 only in that they do not mention superelastic materials or shape memory alloys for the longitudinal element. These are however a simple matter of design choice available to the skilled person when designing instruments for cleaning of root canals, and the benefits from using these materials are easily foreseeable in advance. In fact shape memory alloys and superelastic alloys are very common materials used in manufacturing dental applications. Similarly in claim 26, the shape of the longitudinal elements is also a simple, non-inventive design choice for the

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(SEPARATE SHEET)**

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skilled person.

3. Claims 1-23, 27 are deemed to satisfy the requirements of novelty, inventive step and industrial applicability since the prior art available neither discloses, nor fairly implies, the use of a lattice-type structure of the form, shape and material properties described therein.

Claims

1. An instrument for cleaning and/or shaping and/or widening a channel that exists in or through a solid object;
characterized in that at least of portion of the body of said instrument is comprised of longitudinal elements and circumferential elements that connect adjacent longitudinal elements, thereby defining the three dimensional shape of said portion of said body, such shape being an empty volume surrounding the longitudinal axis, said volume bounded radially by a wall having an open lattice-like structure, and wherein the design of said instrument and the material from which it is made allows said volume, the outer contour of said instrument, or both to change during use in order to shape said instrument to the three dimensional contour of said channel.
2. An instrument according to claim 1, wherein the design of said instrument and the material of which said instrument is made allows the outer contour of said instrument to change during use to conform to the perimeter of the local cross section of the channel at any radial plane located along the length of said instrument that is inserted into said channel.

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3. An instrument according to claim 1, wherein said instrument is made from a superelastic material.
4. An instrument according to claim 1, wherein said instrument is made from material having shape memory properties.
5. An instrument according to claim 4, wherein the material of which said instrument is made is treated after said instrument is produced to give it shape memory properties.
6. An instrument according to claim 3, wherein the superelastic material is a nickel titanium alloy.
7. An instrument according to claim 4, wherein the instrument having shape memory properties is made from a nickel titanium alloy.
8. An instrument according to claim 1, wherein the design of said instrument and the material of which said instrument is made allows a single instrument to be inserted into the channel and used for the entire procedure of cleaning and/or shaping and/or widening said channel before being withdrawn.

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9. An instrument according to claim 1, wherein, if said instrument breaks inside the channel, a specially designed extractor is used to withdraw the broken piece of said instrument from said channel without causing damage to the solid object.
10. An instrument according to claim 1, wherein the three-dimensional shape of the longitudinal and circumferential elements is chosen from the group comprising:
 - blade shaped;
 - polygonal prism shaped;
 - rod shaped;
 - curved shaped; and
 - round shaped.
11. An instrument according to claim 1, wherein the longitudinal and circumferential elements have a cross-sectional shape chosen from the group comprising:
 - polygonal;
 - round;
 - curved; and
 - blade-shaped.

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12. An instrument according to claim 1, wherein the longitudinal elements have a shape selected from the group comprising:
 - straight elements; and
 - curved elements.
13. An instrument according to claim 1, wherein the circumferential elements have a shape selected from the group comprising:
 - straight elements; and
 - curved elements.
14. An instrument according to claim 1, wherein at least a part of the outer surface of said instrument is constructed or modified in one of the ways selected from the following group:
 - a. at least part of the outer surface of said instrument is coated with a coating of a abrasive material;
 - b. at least part of the outer surface of said instrument is roughened;
 - c. at least part of the outer surface of said instrument comprises numerous small teeth; and,
 - d. at least part of the outer surface of said instrument comprises a cutting edge;

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thereby allowing said instrument to remove material from the wall of the channel when relative motion takes place between said outer surface and said wall.

15. An instrument according to claim 14, wherein the abrasive material is chosen from the group comprising:
 - diamond powder;
 - titanium nitride; and
 - tungsten carbide.
16. An instrument according to claim 14, wherein the relative motion is chosen from the group comprising:
 - rotation;
 - translation;
 - vibration; and
 - a combination of two or more of these motions.
17. An instrument according to claim 1, wherein debris resulting from the cleaning and/or shaping and/or widening can be removed from the channel while said instrument is inserted and working in said channel as a result of one or both of the following features of the design of said instrument:

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- a. said instrument is designed such as to have a hollow interior through which said debris may be withdrawn; and,
 - b. said instrument is designed such as to have at least some of the circumferential elements project radially outward from the longitudinal elements, thereby creating a space through which said debris may be withdrawn.
18. An instrument according to claim 17, wherein fluid can flow into the channel through one or both of:
- a. via the interior of said instrument; and,
 - b. via the space between the wall of the channel and the outer surface of said instrument;
- while said instrument is inserted and working in said channel.
19. An instrument according to claim 1, wherein, during the procedure of cleaning and/or shaping and/or widening the channel, a relatively uniform amount of material is removable from the wall of said channel along the entire insertion length of said instrument in said channel.
20. An instrument according to claim 1, wherein, during the procedure of cleaning and/or shaping and/or widening the channel, a different amount of material is removable from the wall of said channel at

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different positions along the insertion length of said instrument in said channel

21. An instrument according to claim 1, wherein the material of which said instrument is made allows said instrument to be inserted into the channel such that it passes through the entire length of said channel.
22. An instrument according to claim 1, wherein said instrument is inserted into the channel such that it passes through only a portion of the entire length of said channel.
23. An instrument according to claim 1, wherein, as a result of the design of said instrument and the material of which said instrument is made the cross-sectional shape of said channel, along the entire insertion length of said instrument that is inserted into said channel, is essentially the same after the procedure of cleaning and/or shaping and/or widening the channel as before said procedure.
24. An instrument for cleaning and/or shaping and/or widening a channel that exists in or through a solid object, characterized in

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that said instrument comprises a long narrow balloon, which is inserted into said channel and then inflated.

25. An instrument for cleaning and/or shaping and/or widening a channel that exists in or through a solid object, characterized in that the body of said instrument is comprised of one longitudinal element from which project radially a multitude of elements, wherein said instrument is made from one or both of the following:
- a. a superelastic material; and,
 - b. a material having shape memory properties;
- thereby allowing the outer contour of said instrument to change during use in order to shape said instrument to the changing three dimensional contour of said channel.
26. An instrument according to claim 25, wherein said elements are selected from the following group:
- a. blade-like; and,
 - b. wire-like.
27. An instrument according to claim 1, wherein said instrument is an endodontic file, the channel is a root canal, and cleaning and/or shaping and/or widening of the channel comprises the cleaning, shaping, and widening stage of a root canal procedure.

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28. A method of using the instrument of claim 1 for cleaning and/or shaping and/or widening a channel that exists in or through a solid object said method comprising the following steps:

- inserting said instrument into said channel;
- causing relative motion between said instrument and the wall of said channel;
- optionally, removing the debris resulting from said cleaning and/or shaping and/or widening from said channel while said relative motion between said instrument and said wall of said channel takes place;
- optionally, causing fluid to flow into said channel while said relative motion between said instrument and said wall of said channel takes place; and
- removing said instrument from said channel when said cleaning and/or shaping and/or widening have been completed.

29. A method of using the endodontic file of claim 27 for cleaning, and/or shaping, and/or widening a root canal, said method comprising the following steps:

- inserting said file into said root canal;
- causing said file to move relative to the wall of said root canal;

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- optionally, removing the debris resulting from said cleaning, shaping, and widening from said root canal while said file moves relative to said wall of said root canal;
 - optionally, causing fluid to flow into said root canal while said file moves relative to said walls of said root canal; and
 - removing said file from said root canal when said cleaning, shaping, and widening have been completed.
30. A method according to claim 28 or claim 29, wherein more than one file is used to clean, and/or shape, and/or widen the channel.

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